

Quotient Limited Reports Second Quarter Fiscal 2021 Results and Business Update

- FDA Emergency Use Authorization for the MosaiQ COVID-19 antibody test received
- FDA 510(k) clearance for Initial MosaiQ SDS microarray and MosaiQ instrument expected before the end of CY2020
- European field trial for Expanded MosaiQ IH microarray progressing; on track for CE Mark submission in Q4 2020
- Binding Letter Agreement for patient transfusion diagnostics signed with Ortho Clinical Diagnostics; eligible for up to \$67.5 million in milestones and arbitration settled
- Double digit growth for Alba by Quotient reagents, reaching high-end of guidance
- Strong cash position following successful completion of public equity offering

JERSEY, Channel Islands, November 2, 2020 (GLOBE NEWSWIRE) -- Quotient Limited (NASDAQ: QTNT), a commercial-stage diagnostics company (Quotient or the Company), headquartered in Eysins, Switzerland, today reported its second quarter fiscal 2021 results and summarized recent key developments.

Quotient obtained an FDA Emergency Use Authorization (EUA) in September 2020 for its high performance MosaiQ COVID-19 antibody microarray. The test detects antibodies generated in response to the SARS-CoV-2 virus. The EUA also applies to the MosaiQ instrument and software when used with the MosaiQ COVID-19 antibody microarray. The test demonstrates the flexibility of the MosaiQ platform, and the high accuracy of the test was confirmed through several external studies. It is available for sale in Europe and the U.S.

The European field trials for the MosaiQ Expanded Immunohematology (IH) microarray are progressing and a submission for CE Mark is planned for the fourth quarter of calendar year (CY) 2020. The Expanded IH microarray is expected to be available for sale in Europe at the end of the first quarter of CY2021. Together with the CE-marked initial MosaiQ Serological Disease Screening (SDS) microarray and MosaiQ instrument, this combination will be the Company's first comprehensive commercial offering for the donor transfusion market.

At the beginning of September 2020, the Company and Ortho Clinical Diagnostics, Inc. (Ortho) signed a binding letter agreement that confirmed the termination of their former distribution agreement, ended the related arbitration between the two companies and established a new distributor relationship focused solely on patient transfusion diagnostics in the U.S. and Europe. Under the letter agreement, in addition to payments for the products it will supply, Quotient will be entitled to milestone payments in the amount of up to \$67.5 million upon the achievement of certain regulatory and commercial sales benchmarks. Ortho paid Quotient the first non-refundable milestone payment of \$7.5 million in September 2020.

The Company also announced double digit growth for Alba by Quotient reagents for the second quarter ended September 30, 2020. MosaiQ COVID-19 antibody microarray sales reached \$0.6 million during the quarter. The COVID-19 antibody microarray sales were primarily driven by sales in the U.S. while demand in Europe remains low.

Following an equity capital raise in September 2020, the Company reports a strong cash position as of September 30, 2020, with cash and cash equivalents of \$171.8 million (including \$9 million in restricted cash reserve accounts). The Company expects this cash position will carry it well into the commercial launch of MosaiQ in the donor transfusion market.

MosaiQ Platform

MosaiQ, Quotient's next-generation platform, is designed to deliver fast immunohematology, serological and molecular disease screening, using a single low volume sample on a high throughput, multimodal multiplexing automated platform. MosaiQ represents a transformative and highly disruptive unified testing system for transfusion diagnostics and beyond. Feasibility to deliver required performance in serological and molecular disease screening has been demonstrated. MosaiQ offers the potential to significantly reduce complexity and improve workflow for our customers. A serological test was developed in April 2020 in response to the global COVID-19 pandemic. The MosaiQ COVID-19 antibody microarray is CE marked and has received FDA EUA, making it available for distribution in the U.S. and Europe, including Switzerland and the UK.

Regulatory and Commercial Milestones

Europe

- Donor IH Field Trials – Results of the Expanded IH microarray field trials in Europe are expected in November 2020. The submission for CE mark is targeted before year-end while the CE mark is anticipated to be obtained by the end of the first quarter of CY2021
- SDS Field Trials – European field trials for the Expanded SDS microarray are targeted to start in the first half of CY2021 with a CE mark submission targeted in the second or third quarter of CY2021
- Commercial Offering – The first comprehensive commercial combination for the donor transfusion market (Initial SDS and Expanded IH microarrays) is expected to be available in Europe at the end of the first quarter of CY2021
- Patient IH – The Company is developing for Ortho an IH microarray for the patient transfusion market and we expect to submit for CE mark in the fourth quarter of CY2021

U.S.

- Donor IH Field Trials – Expanded IH field trials are expected to commence by December 2020 or at the beginning of CY2021
- SDS Regulatory – US FDA 510(k) clearance for the Initial SDS microarray and the MosaiQ instrument is expected before the end of CY2020

Quotient CEO Franz Walt commented “I am very pleased with the recent progress of our development programs. Despite continuing disruption by the global pandemic, we advanced our various development

products and are well-financed as we approach our commercial launch in the donor transfusion market, which we expect in a couple of months. The new letter agreement with Ortho is also an important milestone for our company. I am glad the pending arbitration could be settled and am very much looking forward to collaborating with Ortho in the patient transfusion market.”

Fiscal Fourth Quarter and Full Year Financial Results

The Alba by Quotient reagent business continues to deliver top line growth, with strong product sales of \$8.0 million in the second quarter, up 12.4% from the quarter ended September 30, 2019. This performance was driven by 7.2% growth in sales to original equipment manufacturer (OEM) customers, while direct product sales grew 22.6%. The product sales related to the MosaiQ COVID-19 antibody microarray were \$0.6 million in the second quarter.

Other revenues for the quarter ended September 30, 2020 arose from the recognition of an initial milestone payment of \$7.5 million received from Ortho in respect of the development of a MosaiQ IH microarray optimized for the patient transfusion market. Other revenues in the quarter ended September 30, 2019 arose from the achievement of product development milestones under another development contract, which was completed during the year ended March 31, 2020.

In the quarter ended September 30, 2020, gross margin on product sales increased to 47.3% compared to the gross margin on product sales of 44.1% reported in the quarter ended September 30, 2019. Year over year, gross margin was positively impacted mainly by improved product mix and lower levels of materials scrapped. In addition, the negative impact seen in the first quarter of fiscal 2021 from operating restrictions related to the COVID-19 pandemic were largely resolved in the second quarter.

Key revenue and profit results are summarized below (expressed in thousands, except percentages).

	Quarter Ended		Six Months Ended	
	September 30,		September 30	
	2020	2019	2020	2019
Revenue:				
Product sales —OEM customers	\$ 5,034	\$ 4,696	\$ 11,218	\$ 10,431
Product sales — direct customers and distributors	2,942	2,400	5,571	4,834
Product sales – MosaiQ	567	—	678	—
Other revenues	7,523	750	7,523	750
Total revenue	\$ 16,066	\$ 7,846	\$ 24,990	\$ 16,015
Product sales from standing orders (%)	67%	68%	68%	70%
Gross profit	\$ 11,567	\$ 3,876	\$ 15,077	\$ 7,481
Gross profit as a % of total revenue	72.0%	49.4%	60.3%	46.7%
Gross margin on product sales (%)	47.3%	44.1%	43.2%	44.1%
Operating (loss)	\$ (13,098)	\$ (18,441)	\$ (32,819)	\$ (36,864)

The operating loss for the quarter ended September 30, 2020 included legal and advisory fees of \$1.1 million related to the Company's entry into its letter agreement with Ortho in the second quarter and the termination of the arbitration between the parties.

Capital expenditures totaled \$1.3 million in the quarter ended September 30, 2020, compared with \$1.4 million in the quarter ended September 30, 2019.

On September 15, 2020, the Company completed a public equity offering and raised additional equity of \$80.7 million net of underwriting discounts and other offering expenses of \$5.6 million.

As at September 30, 2020, Quotient had \$171.8 million in cash and other short-term investments (including \$9 million in restricted cash reserve accounts) and \$157.4 million of debt.

Outlook for the Fiscal Year Ending March 31, 2021

- Total product sales of Alba by Quotient reagents are still expected to be in the range of \$32 to \$34 million compared to product sales in fiscal 2020 of \$31.6 million.
- Capital expenditures in the range of \$5 to \$10 million.
- Average monthly cash use for operations in the range of \$5 to \$6 million excluding potential revenue related to COVID-19 antibody test.

Alba by Quotient product sales in the third quarter of fiscal 2021 are expected to be within the range of \$7.8 to \$8.2 million, compared with \$7.6 million for the third quarter of fiscal 2020.

Quotient is unable to reliably forecast sales volumes for its MosaiQ COVID-19 antibody tests because the market for those tests is still developing and industry expectations as to potential demand vary widely. For this reason, Quotient also is not providing guidance on its operating results for the remainder of this fiscal year.

Quarterly product sales can fluctuate depending upon the shipment cycles for red blood cell-based products, which account for approximately two-thirds of current product sales. These products typically experience 13 shipment cycles per year, equating to three shipments of each product per quarter, except for one quarter per year when four shipments occur. The timing of shipment of bulk antisera products to OEM customers may also move revenues from quarter to quarter. Some seasonality in demand is also experienced around holiday periods in both Europe and the United States. As a result of these factors, Quotient expects to continue to see seasonality and quarter-to-quarter variations in product sales.

Conference Call

Quotient will host a conference call on Monday, November 2, 2020 at 8:00 a.m. Eastern Time to discuss its second quarter fiscal 2021 financial results. Participants may access the call by dialing 1-877-407-0784 in the U.S. or 1-201-689-8560 outside the U.S. The access code is 13712034.



The conference call will be webcast live on the Company's website at www.quotientbd.com. Link: <http://public.viaavid.com/player/index.php?id=142003>

A replay of this conference call will be available through November 9, 2020 by dialing 1-844-512-2921 in the U.S. or 1-412-317-6671 outside the U.S. The replay access code is 13712034.

About Quotient Limited

Building on over 30 years of experience in transfusion diagnostics, Quotient is a commercial-stage diagnostics company committed to delivering solutions that reshape the way diagnostics is practiced. MosaiQ, Quotient's proprietary multiplex microarray technology, offers the world's first fully automated, consolidated testing platform, allowing for multiple tests across different modalities. MosaiQ is designed to be a game-changing solution, which Quotient believes will increase efficiencies, improve clinical practice, deliver significant workflow improvements, and operational cost savings to laboratories around the world. A serological test was developed in April 2020 in response to the global COVID-19 pandemic. The MosaiQ COVID-19 Antibody Microarray is CE marked and is the subject of an Emergency Use Authorization issued by the U.S. Food and Drug Administration. The COVID-19 antibody test is available for distribution in the U.S., the EU, the UK and Switzerland. Quotient's operations are based in Eysins, Switzerland, Edinburgh, Scotland and Newtown, Pennsylvania.

Forward-Looking Statements

This news release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. These forward-looking statements may include statements regarding our expectations of continued growth, the development, regulatory approval, commercialization and impact of MosaiQ and other new products (including the potential for using the Company's MosaiQ technology to infectious disease diagnostics), current estimates of third quarter and full year fiscal 2021 operating results and expectations regarding our future funding sources. Such statements are based on current assumptions that involve risks and uncertainties that could cause actual outcomes and results to differ materially. These risks and uncertainties, many of which are beyond our control, include delays or denials of regulatory approvals or clearances for products or applications; market acceptance of our products; the impact of competition; the impact of facility expansions and expanded product development, clinical, sales and marketing activities on operating expenses; delays or other unforeseen problems with respect to manufacturing, product development or field trial studies; adverse results in connection with any future legal proceedings, continued or worsening adverse conditions in the general domestic and global economic markets, including as a result of the global COVID-19 pandemic; as well as the other risks set forth in the Company's filings with the Securities and Exchange Commission. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Quotient disclaims any obligation to update these forward-looking statements. The Quotient logo, Quotient MosaiQ and MosaiQ are trademarks or registered trademarks of Quotient Limited or its subsidiaries in various jurisdictions.

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Quotient Limited
Condensed Consolidated Statements of Comprehensive Loss
(In thousands, except share and per share amounts)
(Unaudited)

	Quarter Ended		Six Months Ended	
	September 30,		September 30,	
	2020	2019	2020	2019
Revenue:				
Product sales	\$ 8,543	\$ 7,096	\$ 17,467	\$ 15,265
Other revenues	7,523	750	7,523	750
Total revenue	16,066	7,846	24,990	16,015
Cost of revenue	4,499	3,970	9,913	8,534
Gross profit	11,567	3,876	15,077	7,481
Operating expenses:				
Sales and marketing	2,231	2,253	4,474	4,833
Research and development, net	12,878	13,083	24,328	24,736
General and administrative expense	9,556	6,981	19,094	14,776
Total operating expense	24,665	22,317	47,896	44,345
Operating loss	(13,098)	(18,441)	(32,819)	(36,864)
Other income (expense)				
Interest expense, net	(6,858)	(7,291)	(12,784)	(13,376)
Other, net	4,998	(1,244)	5,231	(294)
Other expense, net	(1,860)	(8,535)	(7,553)	(13,670)
Loss before income taxes	(14,958)	(26,976)	(40,372)	(50,534)
Provision for income taxes	(17)	(14)	(32)	(27)
Net loss	\$ (14,975)	\$ (26,990)	\$ (40,404)	\$ (50,561)
Other comprehensive income (loss):				
Change in fair value of effective portion of foreign currency cash flow hedges	\$ 279	\$ (158)	\$ 276	\$ (278)
Change in unrealized gain on short-term investments	(79)	47	(483)	194
Foreign currency gain (loss)	(3,447)	(11)	(3,301)	(1,025)
Provision for pension benefit obligation	14	48	27	96
Other comprehensive loss	(3,233)	(74)	(3,481)	(1,013)
Comprehensive loss	\$ (18,208)	\$ (27,064)	\$ (43,885)	\$ (51,574)
Net loss available to ordinary shareholders				
- basic and diluted	\$ (14,975)	\$ (26,990)	\$ (40,404)	\$ (50,561)
Loss per share - basic and diluted	\$ (0.18)	\$ (0.41)	\$ (0.49)	\$ (0.76)
Weighted-average shares outstanding - basic and diluted	83,949,195	66,291,548	82,227,052	66,185,501

Quotient Limited
Condensed Consolidated Balance Sheets
(In Thousands)
(Unaudited)

	September 30, 2020	March 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 18,125	\$ 3,923
Short-term investments	144,618	116,871
Trade accounts receivable, net	4,518	5,402
Inventories	22,798	20,501
Prepaid expenses and other current assets	5,851	3,775
Total current assets	195,910	150,472
Restricted cash	9,031	9,017
Property and equipment, net	39,912	40,165
Operating lease right-of-use assets	21,557	21,493
Intangible assets, net	614	625
Deferred income taxes	237	237
Other non-current assets	4,634	4,454
Total assets	\$ 271,895	\$ 226,463
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$ 5,138	\$ 4,826
Accrued compensation and benefits	5,191	7,210
Accrued expenses and other current liabilities	17,410	15,490
Current portion of long-term debt	12,083	—
Current portion of operating lease liability	3,138	3,033
Current portion of finance lease obligation	577	598
Total current liabilities	43,537	31,157
Long-term debt	145,328	153,024
Operating lease liability, less current portion	20,282	19,914
Finance lease obligation, less current portion	921	1,117
Defined benefit pension plan obligation	7,169	6,353
7% Cumulative redeemable preference shares	20,950	20,425
Total liabilities	238,185	231,990
Total shareholders' equity (deficit)	33,710	(5,527)
Total liabilities and shareholders' equity (deficit)	\$ 271,895	\$ 226,463

Quotient Limited
Condensed Consolidated Statements of Cash Flows
(In Thousands)
(Unaudited)

	Six months ended September 30,	
	2020	2019
OPERATING ACTIVITIES:		
Net loss	\$ (40,404)	\$ (50,561)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation, amortization and loss on disposal of fixed assets	4,128	6,070
Share-based compensation	2,284	2,179
Increase in deferred lease rentals	348	148
Swiss pension obligation	516	383
Amortization of deferred debt issue costs	4,388	5,041
Accrued preference share dividends	525	525
Income taxes	32	27
Net change in assets and liabilities:		
Trade accounts receivable, net	1,093	(1,161)
Inventories	(1,411)	(2,874)
Accounts payable and accrued liabilities	1,898	(83)
Accrued compensation and benefits	(2,215)	(1,764)
Other assets	(1,807)	(648)
Net cash used in operating activities	(30,633)	(42,718)
INVESTING ACTIVITIES:		
Increase in short-term investments	(72,247)	(15,000)
Realization of short-term investments	44,016	38,928
Purchase of property and equipment	(2,069)	(2,558)
Net cash (used in) / generated from investing activities	(30,300)	21,368
FINANCING ACTIVITIES:		
Repayment of finance leases	(358)	(210)
Proceeds from drawdown of new debt	—	25,000
Debt issuance costs and fees paid to noteholders	—	(874)
Proceeds from issuance of ordinary shares and warrants	80,838	377
Net cash generated from financing activities	80,482	24,293
Effect of exchange rate fluctuations on cash and cash equivalents	(5,333)	277
Change in cash and cash equivalents	14,216	3,220
Beginning cash and cash equivalents	12,940	11,603
Ending cash and cash equivalents	<u>\$ 27,156</u>	<u>\$ 14,823</u>
Supplemental cash flow disclosures:		
Income taxes paid	\$ —	\$ —
Interest paid	\$ 8,765	\$ 7,239
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	\$ 18,125	\$ 5,816
Restricted cash	9,031	9,007
Total cash, cash equivalents and restricted cash	<u>\$ 27,156</u>	<u>\$ 14,823</u>